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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,667	12/03/2001	Esteban Masuda	021044-000600US	7585

20350 7590 06/26/2003

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/998,667	MASUDA ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)[·] Responsive to communication(s) filed on *04 June 2003* .

2a)[ ] This action is **FINAL**. 2b)[ ] This action is non-final.

3)[ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)[·] Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *24-46* is/are withdrawn from consideration.

5)[ ] Claim(s) _____ is/are allowed.

6)[ ] Claim(s) _____ is/are rejected.

7)[ ] Claim(s) _____ is/are objected to.

8)[·] Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)[ ] The specification is objected to by the Examiner.

10)[ ] The drawing(s) filed on _____ is/are: a)[ ] accepted or b)[ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)[ ] The proposed drawing correction filed on _____ is: a)[ ] approved b)[ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)[ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)[ ] Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)[ ] All b)[ ] Some * c)[ ] None of:

1.[ ] Certified copies of the priority documents have been received.

2.[ ] Certified copies of the priority documents have been received in Application No. _____ .

3.[ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)[ ] Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) [ ] The translation of the foreign language provisional application has been received.

15)[ ] Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [ ] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) [ ] Interview Summary (PTO-413) Paper No(s). _____ .
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other: .

DETAILED ACTION

This Office Action is a response to the Election filed June 4, 2003, in Paper No. 13.

Claims 1-46 are pending in the instant application.

Claims 1, 22 and 23 have been amended. Claims 24-46 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

Claims 1-23 have been examined to the extent they read on the elected subject matter.

Election/Restrictions

Applicant's election with traverse of Group II (claims 1-23), an *in vitro* method for identifying a compound that modulates T lymphocyte activation, in Paper No. 13 is acknowledged. The traversal is on the ground(s) that Group II, an *in vitro* method for identifying a compound that modulates T lymphocyte activation and Group I, an *in vivo* method for identifying a compound that modulates T lymphocyte activation, should be examined together as both groups require the same method steps and a search of both Groups would not place an undue burden on the Examiner.

Applicant's arguments have been considered and are found persuasive. Group I, an *in vivo* method for identifying a compound that modulates T lymphocyte activation and Group II, an *in vitro* method for identifying a compound that modulates T lymphocyte activation, will be examined together.

However, after reconsideration of the elected invention, it has been determined that the elected invention contains multiple inventions and further restriction is required as follows:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, drawn to a method for identifying a compound that modulates T lymphocyte activation, wherein the compound is an antibody, comprising contacting the compound with a TRAC1 polypeptide and determining the functional effect of the compound upon the TRAC1 polypeptide, classifiable in class 435, subclass 7.24.

II. Claims 1-16 and 18, drawn to a method for identifying a compound that modulates T lymphocyte activation, wherein the compound is an antisense molecule, comprising contacting the compound with a TRAC1 polypeptide and determining the functional effect of the compound upon the TRAC1 polypeptide, classifiable in class 435, subclass 6.

II. Claims 1-16 and 19, drawn to a method for identifying a compound that modulates T lymphocyte activation, wherein the compound is a small organic molecule, comprising contacting the compound with a TRAC1 polypeptide and determining the functional effect of the compound upon the TRAC1 polypeptide, classifiable in class 435, subclass 7.24.

IV. Claims 1-16, 20 and 21, drawn to a method for identifying a compound that modulates T lymphocyte activation, wherein the compound is a peptide molecule, comprising contacting the compound with a TRAC1 polypeptide and determining the functional effect of the compound upon the TRAC1 polypeptide, classifiable in class 435, subclass 4.

V. Claim 22, drawn to a method for identifying a compound that modulates T lymphocyte activation, comprising contacting the compound with a TRAC1 polypeptide and

determining the chemical or phenotypic effect of the compound upon a cell comprising a TRAC1 polypeptide, classifiable in class 435, subclass 4.

VI. Claim 23, drawn to a method for identifying a compound that modulates T lymphocyte activation, comprising contacting the compound with a TRAC1 polypeptide and determining the physical effect of the compound on the TRAC1 polypeptide and determining the chemical or phenotypic effect of the compound upon a cell comprising a TRAC1 polypeptide, classifiable in class 435, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-IV are unrelated each from the other. The different inventions are unrelated as outlined above because each Group requires different inhibitors/modulators that are not structurally related, have different modes of operation, and are likely to modulate their target's activity to varying degrees. For example, the antisense compound of Group II are nucleic acid molecules, and act on their targets by hybridizing to said targets, thus causing its cleavage by RNAse H. The antibody of Group I, the peptide molecule of Group IV, or the small organic molecule of Group I possess none of these features or functions. The antibody of Group I is different from the peptide molecule of Group IV and the small organic molecule of Group II because all antibodies have a defined chemical core structure, and can be made to target almost any exposed portion of the target's tertiary structure, which are not characteristic of all small organic molecules or all peptide molecule inhibitors/modulators. Moreover, the small organic molecule inhibitor/modulator of Group III share virtually no significant structural homology with the peptide molecule inhibitor/modulator of Group IV. Because these inventions utilize

structurally and functionally distinct molecules for the reasons given above and because the search required for Groups I-IV are not required one for the other, restriction for examination purposes as indicated is proper. Furthermore, a search and examination of these methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject inhibitors/modulators require divergent assays and steps.

Although the methods of Groups I-IV and V are related because they involve a method for identifying a compound that modulates T lymphocyte activation, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons: Groups I-IV are drawn to a method for identifying a compound that modulates T lymphocyte activation and determining the functional effect of the compound upon the TRAC1 polypeptide and are thus materially different from the method for identifying a compound that modulates T lymphocyte activation and determining the chemical or phenotypic effect of the compound upon a cell comprising a TRAC1 polypeptide of Group V so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of determining the functional effect of the compound upon the TRAC1 polypeptide of Groups I-IV would not encompass all of the art relevant to determining the chemical or phenotypic effect of the compound upon a cell comprising a TRAC1 polypeptide of Group V. Thus, the steps required of Groups I-IV would be materially different and are not required of Group V, and a search and examination of these methods in one patent application would result in an undue burden, since the

searches for the methods are not co-extensive, the classification is different, and the subject matter and steps are divergent. Thus, they are patentably distinct from each other.

Although the methods of Groups I-IV and VI are related because they involve a method for identifying a compound that modulates T lymphocyte activation, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons: Groups I-IV are drawn to a method for identifying a compound that modulates T lymphocyte activation and determining the functional effect of the compound upon the TRAC1 polypeptide and are thus materially different from the method for identifying a compound that modulates T lymphocyte activation, determining the physical effect of the compound on the TRAC1 polypeptide, and determining the chemical or phenotypic effect of the compound upon a cell comprising a TRAC1 polypeptide of Group VI so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of determining the functional effect of the compound upon the TRAC1 polypeptide of Groups I-IV would not encompass all of the art relevant to determining the physical effect of the compound on the TRAC1 polypeptide or determining the chemical or phenotypic effect of the compound upon a cell comprising a TRAC1 polypeptide of Group VI. Thus, the steps required of Groups I-IV would be materially different and are not required of Group VI, and a search and examination of these methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter and steps are divergent. Thus, they are patentably distinct from each other.

Although the methods of Groups V and VI are related because they involve a method for identifying a compound that modulates T lymphocyte activation, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons: Group V is drawn to a method for identifying a compound that modulates T lymphocyte activation and determining the chemical or phenotypic effect of the compound upon a cell comprising a TRAC1 polypeptide and is thus materially different from the method for identifying a compound that modulates T lymphocyte activation, and determining the physical effect of the compound on the TRAC1 polypeptide and determining the chemical or phenotypic effect of the compound upon a cell comprising a TRAC1 polypeptide of Group VI so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of determining the chemical or phenotypic effect of the compound upon a cell comprising a TRAC1 polypeptide of Group V would not encompass all of the art relevant to determining the physical effect of the compound on the TRAC1 polypeptide or determining the chemical or phenotypic effect of the compound upon a cell comprising a TRAC1 polypeptide of Group VI. Thus, the steps required of Group V would be materially different and are not required of Group VI, and a search and examination of these methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter and steps are divergent. Thus, they are patentably distinct from each other.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-8693 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg
June 19, 2003

KAREN LACOURCIERE
PATENT EXAMINER